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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/003,853	11/02/2001	Ashok V. Joshi	4729US	7449

24247 7590 10/20/2004

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EXAMINER

DESANTO, MATTHEW F

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/003,853	JOSHI, ASHOK V.	
	Examiner	Art Unit	
	Matthew F DeSanto	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 23-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21, 23, 25-35 and 37 is/are rejected.
- 7) ☒ Claim(s) 24, 36 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claim 1-1 1, 13, 17-2 1,23,and 25-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Roberts et al. (USPN 6,001,088)

Roberts et al. teaches an iontophoresis method and apparatus for opthamalic delivery of a beneficial agent comprising two electrodes (10, 11), connected to a power source (12), and both configured to contain the beneficial agent that is to be delivered subcutaneously to the patient. The electrode has semi-permeable membrane (column 4, line 64) that contact with an ionic fluid of the patient. Contact of the membranes with the subject's tissue completes the circuit of the device.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claim 12 rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts et al. as applied to claims above, and further in view of Haak et al. (USPN 5,445,606)

Robert et al., as described above, teaches a device for eye delivery of a beneficial agent comprising two electrodes, but fails to teach a control circuit.

Haak et al. teaches a device for the delivery of a medicament comprising two electrodes with semi-permeable membranes and agent reservoirs and a battery and control circuit (31) connected to both electrodes.

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the invention of Roberts et al. with the teachings of Haak et al. because Haak et al. includes a control circuit connected between the electrodes in order to control the amount of current delivered to them, thus affecting the rate of drug delivery for a more effective treatment.

5. Claims 14-16, 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roberts et al. as applied to the claims above, and further in view of Theeuwes et al. (EP 0 931 564).

Roberts, as described above, teaches a device for eye delivery of a beneficial agent comprising two electrodes, but fails to teach the material of the electrodes.

Theeuwes et al. teaches an iontophoretic agent delivery device comprising carbon or titanium electrodes (column 8, lines 12- 13).

It would have been obvious to one skilled in the art at the time of the invention to use a carbon electrode, as such is standard in the art.

Response to Arguments

6. Applicant's arguments filed 8/4/04 have been fully considered but they are not persuasive.
7. The applicant argues two main issues with regards to the Roberts et al. The first issue being that a battery is not formed and a second issue of not implanting the device.
8. With regards to the first issue, a battery is formed. A battery by definition is a group of two or more cells connected together to furnish electric current, which is what the electrodes are doing. They are passing an electric current to one another, thus acting like cells and forming a battery. Another note with regards to this issue, according to the MPEP section 2114 an apparatus claim must have structural or element limitations that are different than the prior art in order to obtain a patent.
9. With regards to the second issue of not implanting the electrodes in the skin, the examiner disagrees and goes to the specification of Roberts et al. to find support. In column 4, lines 26, 27, 32-34, and 56-59 all discuss the ability to implant the electrode in the body.
10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (703) 308-2698. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Matthew DeSanto
Art Unit 3763
October 18, 2004



NICHOLAS D. LUCCHESI
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TECHNOLOGY CENTER 3700